

Implants and restorations without interconnecting abutments in the posterior region: a 1-year prospective case series study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22700

Source

Nationaal Trial Register

Brief title

Matrix study

Health condition

The missing tooth is a molar in maxilla or mandible

Sponsors and support

Primary sponsor: UMCG

Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

- evaluation of technical complications of screw-retained full-anatomic zirconia crowns

without abutment in the posterior maxilla and mandible during a 1-year follow-up.

Secondary outcome

- Implant survival
- Peri-implant bone level change
- Probing pocket depth
- Amount of plaque
- Mucosa condition
- Patient satisfaction

Study description

Background summary

- Background

Implant-supported single crowns are still prone to some complications. Technical complications are breakage of the porcelain and mobility of the crown due to loosening of the screw. Of monolithic zirconia restorations is almost no fracture reported because no porcelain is used. To reduce loosening of the screw-retention, a number of possibilities has been developed. A better fit of the connection between implant and crown and the absence of an extra abutment between implant and crown have resulted in less loosening. Studies evaluating these three developments in one study design are limited.

- Main research question

The primary objective of the study is evaluation of technical complications of screw-retained full-anatomic zirconia crowns without abutment in the posterior maxilla and mandible during a 1-year follow-up.

- Design (including population, confounders/outcomes)

The study design is a prospective observational study of a group of patients which will be treated with a dental implant and a full-zirconia implant-supported crown without abutment because of a missing tooth in the posterior region. Outcomes: primary outcome is the frequency of technical complications; secondary outcome measures will be implant survival, peri-implant bone level change, peri-implant mucosa health and patients' satisfaction using a questionnaire.

Study objective

Absence of technical complications, high implant survival, stable peri-implant bone levels, and satisfied patients.

Study design

Evaluation at 1-year follow-up

Intervention

Dental implant placement and restoration without interconnecting abutment

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria:

- Patients referred to the department of Oral and Maxillofacial Surgery (UMCG) because of having a missing tooth in the posterior region.
- The patient is 18 years or older;
- The missing tooth is a molar in maxilla or mandible;
- Sufficient healthy and vital bone to insert a dental implant with a minimum length of 8 mm and at least 4.0 mm in diameter with initial stability > 45 Ncm
- The implant site is free from infection;
- Adequate oral hygiene (modified plaque index and modified sulcus bleeding index ≤ 1);
- Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration;
- The patient is capable of understanding and giving informed consent.

Exclusion criteria

Exclusion criteria:

- Medical and general contraindications for the surgical procedures;
- Presence of an active and uncontrolled periodontal disease;
- Bruxism;

- Smoking
- A history of local radiotherapy to the head and neck region.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	20-04-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9418
Other	METc UMCG : METc 2021/253 Ref M21.274463

Study results

Summary results

Manuscript with 1-year results